K122916

OCT 19 2012

510(k) SUMMARY

General Information:

Date of Summary Preparation:	September 20, 2012
Name and Address of Manufacturer:	MEDRAD, Inc. 9055 Evergreen BLVD NW Minneapolis, MN 55433-8003
Contact Person:	Brit Baird Regulatory Affairs Manager Phone: 425-636-4137 Fax: 425-636-4001
Device Trade Names:	JETSTREAM Navitus® L System JETSTREAM Navitus® System JETSTREAM G3® SF System JETSTREAM G3® SF 1.6 System
Common Name:	Peripheral Atherectomy Catheter
Regulation Number:	21 CFR 870.4875
Regulation Name:	Intraluminal Artery Stripper
Regulatory Class:	Class II
Classification Panel:	Cardiovascular
Product Code:	MCW

Performance Standards: Performance Standards do not currently exist for these devices. None are established under Section 514.

Device Description: The Jetstream Systems are rotational atherectomy catheter systems designed with either a fixed (Jetstream G3 SF, Jetstream G3 SF 1.6) or an expandable (Jetstream Navitus L, Jetstream Navitus) cutting tip intended for use in debulking and treating vascular disease in the peripheral vasculature. Separate lumens within the Catheter allow for continuous aspiration and infusion during device use. Excised tissue, thrombus, and fluid are aspirated from the peripheral treatment site through a port in the Catheter tip to an external collection bag located on the Console. The distal portion of the Catheter also possesses infusion ports that provide continuous infusion of sterile saline during the atherectomy procedure.

The Jetstream Systems consist of two primary components: a Catheter with Control Pod and a Console, which are packaged separately. Each of these system components is described generally as follows:

- **Jetstream Catheter with Control Pod:** A sterile, single-use unit consisting of an electrically-driven Catheter with attached Control Pod. As with the predicate device, the modified Jetstream Catheter utilizes a differentially cutting tip and includes both aspiration and infusion capabilities and the Control Pod provides a user interface with keypad controls. The unit, its electrical connectors, tubing, and aspirant collection bag are packaged in a double pouched tray.

- **PV Console:** A reusable compact PV Console, with two (2) peristaltic pumps for aspiration and infusion, power supply, system controller, keypad interface, and LED indicators for device operational status. The PV Console mounts on a standard I.V. stand and remains outside the sterile field during the procedure.

The primary modification of this 510(k) removes the tachometer function (i.e., speed/RPM input) in the Control Pod, and correspondingly removes the rotational speed displays on the PV Console. This modification applies to the entire family of Jetstream Systems.

Indications for Use: The JETSTREAM System is intended for use in atherectomy of the peripheral vasculature and to break apart and remove thrombus from upper and lower extremity peripheral arteries. It is not intended for use in coronary, carotid, iliac or renal vasculature.

Substantially Equivalent Devices: MEDRAD cites the following devices as the primary predicate devices for the aforementioned modification and substantial equivalence basis.

Primary Predicate Devices	Pathway Medical Predicate 510(k)
JETSTREAM Navitus® L System	K120242
JETSTREAM Navitus® System	K110626
JETSTREAM G3® SF System	K110626
JETSTREAM G3® SF 1.6 System	K111229

However, the design rationale for and device testing of the modified devices also includes references to the additional predicate devices listed in the table below:

Other Predicate Devices	Pathway Medical Predicate 510(k)
JETSTREAM G3® SF System	K101334
JETSTREAM Pathway PV™ Atherectomy System	K082186
Pathway PV™ Atherectomy System	K081328

Testing Summary: To demonstrate substantial equivalence of the modified Jetstream Systems to the predicate Jetstream Systems, the technological and performance characteristics were evaluated using *in vitro* testing for the primary modification, as outlined below:

- System Reliability/Life Test
- Aspiration Efficiency & Crossing Time
- Label Cleanability and Durability
- Auditory Feedback

The results from these tests:

- demonstrate that the technological and performance characteristics of the modified Jetstream Systems are comparable to the predicate Jetstream Systems,
- support the safety and effectiveness of the modification that is the subject of this 510(k), and
- ensure the modified devices can perform in a manner equivalent to the predicate Jetstream Systems with the identical intended use.

Conclusion (Statement of Equivalence): The data and information presented within this submission (including *in vitro* testing) and the similarities between the modified and predicate devices support a determination of substantial equivalence, and therefore market clearance of the modified Jetstream Systems through this 510(k) Premarket Notification.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 19 2012

Medrad, Inc.
c/o Mr. Brit Baird
Regulatory Affairs Manager
9055 Evergreen Blvd NW
Minneapolis, MN 55433

Re: K122916
Trade/Device Name: Jetstream Navitus L System, Jetstream Navitus System, Jetstream G3 SF System, and Jetstream G3 SF 1.6 System
Regulation Number: 21 CFR 870.4875
Regulation Name: Intraluminal Artery Stripper
Regulatory Class: Class II (two)
Product Code: MCW
Dated: September 20, 2012
Received: September 21, 2012

Dear Mr. Baird:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K122916

Device Name: JETSTREAM Navitus® L System
JETSTREAM Navitus® System
JETSTREAM G3® SF System
JETSTREAM G3® SF 1.6 System

Indications for Use: The JETSTREAM System is intended for use in atherectomy of the peripheral vasculature and to break apart and remove thrombus from upper and lower extremity peripheral arteries. It is not intended for use in coronary, carotid, iliac or renal vasculature.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K122916